Remarks

Claims 13, 61-68, 70-73, 75-77, and 79 are pending in this application upon entry of the claim amendments presented herein. Claims 14-15, 58-59, 69, 74, and 78 are canceled in this paper without prejudice to Applicants' right to pursue the subject matter recited by the claim in one or more divisional, continuation, and/or continuation-in-part applications. Applicants note that claims 68 and 70-75 are currently withdrawn from consideration. These claims are not deleted from this application because a request for rejoinder will be filed at an appropriate time.

Claim 13 is amended to recite, in part, the administration of optically pure (S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-3-morpholinol[1] for the treatment of alcohol addition, a bipolar or manic condition, bulimia, chronic fatigue syndrome, narcolepsy, premenstrual syndrome, or neuropathic pain. The recitation of "an anxiety disorder" and "seasonal affective disorder" are deleted as described in more detail below, and the recitation of "neuropathic pain" is added.[2] Support for this addition can be found, for example, on pages 29-30 (Example 6) of the specification.

Claims 61-68, 70-73, and 75-77 are amended to bring them in conformance with amended claim 13. No new matter has been added.

Applicants respectfully submit that the pending claims are allowable at least for the following reasons.

A. Applicants' Statement of Substance of Interview

An in-person interview was held between the Examiner and Hoon Choi, Attorney for Applicants, on May 8, 2007. Applicants thank the Examiner for the courtesy she extended to Attorney for Applicants during the interview.

The rejection of the claims under 35 U.S.C. § 103, which is the only remaining rejection in this application, was discussed. Specifically, Attorney for

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[1] The specific bupropion metabolite recited by claim 1 is intended to be (S,S)-hydroxybupropion, which was originally recited by now canceled claim 15. Please note that the chemical name has been amended (*i.e.*, (S,S)-2-(3-chlorophenyl)-2-hydroxy-3,5,5-trimethyl-morpholinol to (S,S)-2-(3.chlorophenyl)-3,5,5-trimethyl-2-morpholinol) to remove any purported ambiguity in the chemical name originally recited by the claims. Support can be found, for example, on page 2, scheme 2 and page 8, line 31 – page 9, line 2 of the specification.

[2] The treatment of "neuropathic pain" is also recited by newly added dependent claim 79.

Applicants brought to the Examiner's attention certain U.S. patents, namely U.S. Patent Nos. 6,734,213; 6,998,400; and 7,098,206. Attorney for Applicants pointed out that those U.S. patents issued with claims substantially identical to some of the claims pending in this application, and that the priority dates for those issued claims are later than that of the currently pending claims. It was also mentioned that an interference is potentially contemplated in connection with this application and those patents.

The Examiner suggested that claim 13 should be amended to recite specific bupropion metabolite, *i.e.*, (S,S)-hydroxybupropion. The Examiner also suggested that certain indications recited by claim 13 be deleted. Attorney for Applicants agreed to submit the suggested claim amendments, which are reflected in this paper.

B. Response to Office Action

Applicants appreciate the Examiner's withdrawal of the rejection under 35 U.S.C. § 112, which was raised in the previous office action. However, rejection of the claims under 35 U.S.C. § 103 is maintained in the Office Action. Applicants respectfully submit that all of the claims are allowable for at least the following reasons.

On pages 2-6 of the Office Action, claims 13-15, 58-59, 61-67, 69, and 76-78 are rejected as allegedly obvious over the abstract of Simeon *et al.*, *Canadian Journal of Psychiatry*, 31(6): 581-5 (1986) ("Simeon") in view of U.S. Patent No. 6,274,579 to Morgan *et al.* ("Morgan"). In particular, the Examiner alleges that the claims are obvious based on the assertion that: 1) Simeon teaches that "bupropion shows significant improvements of anxiety, hyperactivity,... conduct disorder, etc." (Office Action, page 4); and 2) although Simeon does not disclose (S,S)-2-(3-chlorophenyl)-3,5,5,-trimethyl-2-morpholinol ("(S,S)-hydroxybupropion"), Morgan discloses that (S,S)-hydroxybupropion is active metabolite of bupropion. (Office Action, page 5). Applicants respectfully traverse this rejection.

First, Applicants respectfully point out that the Examiner's assertion that Simeon discloses that "bupropion shows significant improvement of anxiety, hyperactivity, ...conduct disorder, etc." is moot. This is because, apart from Applicants submission provided in their previous response of December 7, 2006, what Simeon may or may not disclose with regard to "anxiety, hyperactivity,...conduct disorder" is

irrelevant in view of the fact that claim 13 does not recite "anxiety disorder."[3] For this reason alone, Applicants respectfully request that the rejection of the claims be withdrawn.

In addition, even assuming, *arguendo*, that Simeon somehow disclosed or suggested the use of bupropion for the treatment of any of the disorders recited by claim 13, which it does not, Morgan would not have led those of ordinary skill in the art to replace bupropion with (S,S)-hydroxybupropion. In this regard, Applicants respectfully point out that although Morgan reports that the anti-depressant activity of racemic bupropion is likely to result from (S,S)-hydroxybupropion, it does not provide any disclosure or suggestion that bupropion may be replaced with (S,S)-hydroxybupropion in any and all methods where bupropion is used.

For example, Morgan discloses that, while (S,S)-hydroxybupropion "was approximately twice as potent as [racemic bupropion] as an NA inhibitor," it was "approximately 10-fold less potent as an inhibitor of dopamine uptake." (Morgan, col. 7, lines 25-29). Therefore, at most, Morgan merely shows that (S,S)-hydroxybupropion has different, but not necessarily more desirable, pharmacological properties than racemic bupropion. Thus, Morgan sets forth a list of specific disorders against which (S,S)-hydroxybupropion may be used, none of which is a disorder recited by the pending claims. (*See* Morgan, Abstract and col. 2, lines 46-63).

Further in this regard, Morgan clearly discloses that "the mechanism of action of bupropion, as with other antidepressants, is unknown." (Morgan, col. 1, lines 24-25) (emphasis added). Therefore, by disclosing that bupropion's mechanism of action was not well-understood, and that (S,S)-hydroxybupropion has properties merely different than those of bupropion, Morgan certainly would not have taught or suggested to those skilled in the art that (S,S)-hydroxybupropion can replace bupropion in all of the uses contemplated for bupropion, much less in the methods recited by the pending

[3] In this regard, Applicants wish to make it clear in the record that the recitation of "anxiety disorder" and other disorders is removed from claim 13 solely to expedite the prosecution of this application. Thus, Applicants expressly incorporate herein by reference the discussion provided by Applicants on pages 5-6 of their December 7, 2006 Response, and maintain that claim 13, as was pending at the time of the previous Office Action, is not obvious over, in part, Simeon.

claims.[4] For this additional reason, Applicants respectfully submit that the rejection of the claims should be withdrawn.

Conclusion

For at least the foregoing reasons, Applicants respectfully submit that all of the pending claims are in allowable condition, and thus request that the rejection of the pending claims be withdrawn.

No fee is believed due for this submission. Should any fees be due for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date June 6, 2007

L0209

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[4] Again, Applicants respectfully point out that the combination of Simeon and Morgan does not even teach or suggest that bupropion, much less (S,S)-hydroxybupropion, may be used to treat the disorders recited by the pending claims. Therefore, even assuming that those skilled in the art were somehow led to believe that bupropion can be replaced by (S,S)-hydroxybupropion, in view of the fact that combination of references lacks the disclosure of the use of bupropion itself for the treatment of the disorders recited by the pending claims, the pending claims cannot be obvious.